Recipharm

EXPLORING NEW PROPELLANTS FOR pMDIs

Recipharm Inhalation Solutions™

In 1987, the Montreal Protocol prohibited the use of chloroflurocarbons (CFCs), which have historically been used in inhalation devices to facilitate the delivery of medicines. These were eventually replaced by hyrdofluorocarbons (HFAs) or F-gases. However, HFAs also have a large impact on global warming due to their high Global Warming Potential (GWP) and long atmospheric life (AL). As a result, in 2016, the Kigali Amendment to the Montreal Protocol was agreed by the United Nations. The amendment aims to phase down global HFA consumption by 80–85% by 2047.

While there is currently no legal requirement to change propellants in pMDIs, it is likely HFAs will become more difficult to procure with time as suppliers cut down on their production. Therefore, it is vital to have viable alternatives to ensure continued supply of critical medicines delivered in pMDIs.

At Recipharm, we are taking a proactive approach to the situation and will be ready to adapt to any future changes of legislations, as well as supply challenges.

Our areas of expertise:

- Release analysis – we work with common propellants (HFA227 and HFA134a), as well as the new generation of propellants (ID, assay, related substances, water, acidity, non-volatile matter and non-condensable gases)
- Analytical method development – tailored to specific needs
- Optimisation of container closure system – mathematic modelling and optimisation with the new generation propellants
- Extractables and leachables – comprehensive E&L studies designed to consider both device and drug product
- Formulation evaluation – the effect on the drug product from changing propellants
- Formulation development – formulation development services to support change of propellants or new product development
- Manufacturing – pMDI manufacturing with conventional propellants and process modification for next generation propellants

At Recipharm we offer:

- Problem solvers and depth of knowledge: Our team has the depth of knowledge required to both understand and overcome the challenges associated with developing and manufacturing inhalation products
- An integrated mindset: The team develops drug products with both the device and commercial manufacture in mind. We understand the challenges of commercial manufacturing and can overcome hurdles, reducing time to market
- Regulatory experience: As a global CDMO with facilities previously owned by big pharma, Recipharm is at the forefront of global compliance requirements for inhalation products
- An end-to-end service for inhalation products and devices: From early stage development through to commercial manufacturing for MDIs, DPIs and nasal sprays

The Recipharm approach

The change of propellant in a current pMDI product is a large scope of work which will take several years to perform, including generating the necessary stability data and clinical results. Hence, it is important to consider this challenge in near term strategic plans for any pMDI company.

At Recipharm we're working with suppliers and pharmaceutical companies to prepare for the upcoming propellant changes that will impact the pharma industry by exploring the impact on container closure systems, reformulation and analytical requirements, safety measures, process scale-up and the necessary dossier updates.

Recipharm Inhalation Solutions™

Recipharm is a leading CDMO in the inhalation space, with a long history in inhalation drug product and device development and manufacturing. Recipharm offers an end-to-end service for inhalation drug products and devices from early stage development through to commercial manufacturing for MDIs, DPIs and nasal sprays.

Delivering market leading design, development, and the manufacturing of drug delivery devices to the global pharmaceutical market, in conjunction with Bespak by Recipharm, the integrated CDMO can comprehensively cater for, inhaler, nasal and auto-injector projects, as well as providing access to a team of experts with decades of expertise that allows them to manage complexity and accelerate routes to market. These expertise form part of Recipharm's Inhalation Solutions™, an end-to-end solution spanning early phase development to commercial manufacture.

As a global CDMO, Recipharm is at the forefront of global compliance requirements for inhalation products.
For more information, please visit: recipharm.com

About Recipharm: Recipharm is a leading contract development and manufacturing organisation (CDMO) headquartered in Stockholm, Sweden. We operate development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, the UK and the US and are continuing to grow and expand our offering for our customers.

Employing around 9,000 people, we are focused on supporting pharmaceutical companies with our full service offering, taking products from early development through to commercial production. For over 25 years we have been there for our clients throughout the entire product lifecycle, providing pharmaceutical expertise and managing complexity, time and time again. Despite our growing global footprint, we conduct our business as we always have and continue to deliver value for money with each customer's needs firmly at the heart of all that we do. That's the Recipharm way.

For more information contact: info@recipharm.com

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